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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/567,866	09/21/2006	Yuji Ishida	0230-0233PUS1	2073

2292 7590 12/04/2009
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EXAMINER

FOX, DAVID T

ART UNIT	PAPER NUMBER
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1638

NOTIFICATION DATE	DELIVERY MODE
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12/04/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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Office Action Summary	Application No. 10/567,866	Applicant(s) ISHIDA, YUJI	
	Examiner David T. Fox	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 September 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 September 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Effective Filing Date

The Examiner appreciates Applicant's clarification that the effective filing date of the instant application is 05 August 2004, the filing date of the PCT application.

Applicant's Response

Applicant's amendments and accompanying arguments of 02 September 2009 have obviated all objections and rejections not repeated below.

Applicant's Exhibits B-C of 02 September 2009 are not probative because they have not been submitted in the form of declarations under 37 CFR 1.132. Applicant is invited to resubmit the information set forth in Exhibits B-C as Rule 132 declarations.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Non-Statutory Double Patenting

Claims 1, 3-9 and 12-16 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 12, 14-15, 17-18, 20-21, and 23-24 of **copending Application No. 10/089,695**. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the reasons set forth on page 4 of the last Office action for claims 1, 4-9 and 12-15. It is now considered that the instantly claimed broad ranges of pressures and pressure durations would have been an inherent property of the centrifugation speeds and durations claimed in the copending application. Moreover, it is now considered that the modification of centrifugation speeds to obtain the instantly claimed range of pressures would have been obvious to the artisan of ordinary skill, in the absence of

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unexpected results; if in fact the instantly claimed pressures were not inherent in the centrifugation speeds claimed in the copending application.

Claims 1, 3-9 and 12-16 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 22-29 of **copending Application No. 10/089,696**. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the reasons set forth on page 5 of the last Office action for claims 1, 4-9 and 12-15, and because of the reasons set forth above.

Applicant's arguments filed 02 September 2009 have been fully considered but they are not persuasive. Applicant urges that the amended claims recite the limitations of cancelled claim 2, which was not included in the prior double patenting rejections. The Examiner now considers that such limitations would have been inherent or obvious over the prior art claims, as stated above.

Moreover, it is noted that Applicant's instant specification has demonstrated that centrifugation of maize immature embryos at 15,000 rpm for 10 minutes resulted in enhanced *Agrobacterium*-mediated transformation frequency, as stated in paragraph [0071] bridging pages 33 and 34. Figure 2 of the instant application is not sufficiently clear to distinguish between the results of centrifugation (Figure 2B) versus measured pressure applications (Figures 2C-2D).

Anticipation

Claims 1, 3-6, 8-9 and 12-16 are rejected under 35 U.S.C. 102(b) as being anticipated by **EP 1,306,440** (JAPAN TOBACCO INC published May 2003, Applicant submitted).

The claims are drawn to a method for enhancing *Agrobacterium*-mediated transformation of plant material including immature embryos, said method comprising increasing the pressure exerted on the plant material prior to *Agrobacterium* infection, wherein the pressure is from 1.7 to 10 atmospheres, wherein the pressurization may be performed from 0.1 second to four hours, wherein the pressurization may occur in a liquid, wherein the plant material may be from monocots including rice or maize, and wherein the transformants are selected and optionally regenerated.

EP 1,306,440 teaches a method for enhancing *Agrobacterium*-mediated transformation of rice and maize immature embryos, said method comprising centrifuging said embryos in a liquid for 10 minutes at accelerations of between 100G and 200,000G, followed by selection of the transformants on paromomycin- or hygromycin-containing medium, and regeneration of whole plants. See, e.g., page 3, lines 41-57; page 4, lines 40-49; page 6, line 21 through page 7, line 48; pages 8-10, Tables 1-3 and 5; page 12, line 39 through page 13, line 27.

One of ordinary skill in the art would have recognized that submersion in a liquid and centrifugal force inherently exert the instantly claimed ranges of pressure on the material to which it is applied. It is also noted that the results of instant Example 2 and

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Figure 2 support the Examiner's position of the inherent features and benefits of centrifugation in a liquid, as stated above.

See *In re Best*, 195 USPQ 430, 433 (CCPA 1977), which teaches that where the prior art product seems to be identical to the claimed product, except that the prior art is silent as to a particularly claimed characteristic or property, then the burden shifts to Applicant to provide evidence that the prior art would neither anticipate nor render obvious the claimed invention.

Claims 1, 3-9 and 12-16 are rejected under 35 U.S.C. 102(b) as being anticipated by **EP 1,306,441** (JAPAN TOBACCO INC published May 2003, Applicant submitted).

Claim 7 is drawn to the above method wherein the plant material is heat treated prior to or during *Agrobacterium* infection.

EP 1,306,441 teaches a method for enhancing *Agrobacterium*-mediated transformation of rice and maize immature embryos, said method comprising heating and centrifuging said embryos in a liquid at an acceleration speed of 100G to 200,000G for 1 or 30 or 60 minutes, followed by selection of the transformants on hygromycin- or phosphonothricin-containing medium, and regeneration of whole plants. One of ordinary skill in the art would have recognized that submersion and centrifugal force inherently exert the claimed ranges of pressure on the material to which it is applied, as stated above. See, e.g., page 3, lines 40-47; page 4, lines 4-14; page 6, line 17 through page 7, line 43; pages 8-9, Tables 1-5; page 9, line 49 through page 10.

Claims 1, 3-6, 10 and 13-16 are rejected under 35 U.S.C. 102(b) as being anticipated by **Cheng et al (1996**, Plant Cell Reports 16: 127-132).

Claim 10 is drawn to the above method wherein the plant material is from a dicot.

Cheng et al teach a method for enhancing *Agrobacterium*-mediated transformation of the dicot papaya by submerging callus cells in a carborundum-containing liquid and vortexing the tubes containing the liquid for one minute at high speed, followed by selection of the transformed cells on kanamycin-containing medium, and the regeneration of whole plants (see, e.g., page 128, column 1, bottom paragraph through column 2, first full paragraph; page 132, column 1, penultimate paragraph). One of ordinary skill in the art would have recognized that submersion in a liquid would exert pressure on the submerged material, and that the force of vortexing would also exert pressure thereon. Moreover, one of ordinary skill in the art would have recognized that the collision of the carborundum particles with the papaya callus cells would inherently result in a pressure within the instantly claimed pressure range.

Applicant's arguments filed 02 September 2009 have been fully considered but they are not persuasive. Applicant urges that the amended claims recite the limitations of cancelled claim 2, which was not previously included in the above art rejections. The Examiner now considers that the instantly claimed pressure ranges would have been inherent in the processes taught by the cited prior art, as stated above.

Obviousness

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3-6, 8-9 and 12-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over **EP 1,306,440** (JAPAN TOBACCO INC published May 2003, Applicant submitted).

The claims are drawn to a method for enhancing *Agrobacterium*-mediated transformation of plant material including immature embryos, said method comprising increasing the pressure exerted on the plant material prior to *Agrobacterium* infection, wherein the pressure is from 1.7 to 10 atmospheres, wherein the pressurization may be performed from 0.1 second to four hours, wherein the pressurization may occur in a liquid, wherein the plant material may be from monocots including rice or maize, and wherein the transformants are selected and optionally regenerated.

EP 1,306,440 teaches a method for enhancing *Agrobacterium*-mediated transformation of rice and maize immature embryos, said method comprising centrifuging said embryos in a liquid for 10 minutes at accelerations of between 100G and 200,000G, followed by selection of the transformants on paromomycin- or hygromycin-containing medium, and regeneration of whole plants, as stated above. One of ordinary skill in the art would have recognized that submersion and centrifugal force inherently exert pressure on the material to which it is applied, as stated above.

EP 1,306,440 does not teach the application of pressure from 0.1 second to less than 10 minutes, or from more than 10 minutes to four hours.

It would have been obvious to one of ordinary skill in the art to utilize the centrifugation/pressure mediated method of enhanced *Agrobacterium* transformation taught by EP 1,306,440, and to modify that method by adjusting the length and speed of

the centrifugation, for the optimization of enhanced transformation frequency, in the absence of evidence to the contrary.

Claims 1, 3-9 and 12-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over **EP 1,306,441** (JAPAN TOBACCO INC published May 2003, Applicant submitted).

Claim 7 is drawn to the above method wherein the plant material is heat treated prior to or during *Agrobacterium* infection.

EP 1,306,441 teaches a method for enhancing *Agrobacterium*-mediated transformation of rice and maize immature embryos, said method comprising heating and centrifuging said embryos in a liquid at an acceleration speed of 100G to 200,000G for 1 or 30 or 60 minutes, followed by selection of the transformants on hygromycin- or phosphonothricin-containing medium, and regeneration of whole plants, as stated above. One of ordinary skill in the art would have recognized that submersion and centrifugal force inherently exert the claimed ranges of pressure on the material to which it is applied, as stated above.

EP 1,306,441 does not teach the application of pressure from 0.1 second to less than one minute, from more than one minute to less than 30 minutes, from more than 30 minutes to less than 60 minutes, or from more than 60 minutes to four hours.

It would have been obvious to one of ordinary skill in the art to utilize the centrifugation/pressure mediated method of enhanced *Agrobacterium* transformation taught by EP 1,306,441, and to modify that method by adjusting the length and speed of

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the centrifugation, for the optimization of enhanced transformation frequency, in the absence of evidence to the contrary.

Claims 1, 3-6, 10-11 and 13-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Cheng et al (1996)**.

Claim 11 is drawn to the above method wherein the plant material is the dicot tobacco.

Cheng et al teach a method for enhancing *Agrobacterium*-mediated transformation of the dicot papaya by submerging callus cells in a carborundum-containing liquid and vortexing the tubes containing the liquid for one minute at high speed, followed by selection of the transformed cells on kanamycin-containing medium, and the regeneration of whole plants, as discussed above. One of ordinary skill in the art would have recognized that submersion in a carborundum-containing liquid and vortexing thereof would exert pressure on the submerged material, as stated above.

Cheng et al do not teach the use of tobacco, or pressure durations of 0.1 seconds to less than one minute, or durations of more than one minute to four hours.

It would have been obvious to one of ordinary skill in the art to utilize the submersion and vortexing pressure mediated method of enhanced *Agrobacterium* transformation taught by Cheng et al, and to modify that method by adjusting the duration and speed of the vortexing, for the optimization of enhanced transformation frequency, in the absence of evidence to the contrary. Choice of known, transformable

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dicot species would have also been the optimization of process parameters, within the skill level of the ordinary artisan, in the absence of evidence to the contrary.

Applicant's arguments filed 02 September 2009 have been fully considered but they are not persuasive. Applicant urges that the above references do not teach or reasonably suggest the claimed pressures or durations, or the absence of wounding, for the enhancement of *Agrobacterium*-mediated transformation frequencies. Applicant relies upon experimental data submitted in Exhibits B-C to support his position of unexpectedly high transformation frequencies when utilizing the instantly claimed pressures.

The Examiner maintains that the instantly claimed pressures appear to have been within the level of routine optimization of the prior art pressures, in the absence of evidence to the contrary, as stated above. The benefits of centrifugation have been demonstrated by Applicant in their Example 2 and Figure 2, as stated above. It is noted that the claims do not exclude wounding, and it is unclear whether support for such a recitation exists in the specification. Patentability does not appear to rest on the presence or absence of wounding, as stated below. Moreover, the data presented in Exhibits B-C are not probative, as discussed above.

In addition, Applicant broadly claims pressure ranges of 1.7 to 10 atmospheres, and broadly claims pressure durations of 0.1 second to 4 hours. Applicant may be able to demonstrate unexpected results when utilizing the particular pressure durations and pressure quantities of some of the Examples presented in the instant specification, or when utilizing the particular pressure durations and quantities of some additional

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experiments to be presented in the form of Rule 132 declarations. However, the claims are not so limited.

See In re Lindner, 173 USPQ 356 (CCPA 1972) and In re Grasselli, 218 USPQ 769 (Fed. Cir. 1983) which teach that the evidence of nonobviousness should be commensurate with the scope of the claims.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fox whose telephone number is (571) 272-0795. The examiner can normally be reached on Monday through Friday from 10:30AM to 7:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg, can be reached on 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/David T Fox/

Primary Examiner, Art Unit 1638

December 1, 2009